A PHASE II STUDY OF GEMCITABINE PLUS CISPLATIN CHEMOTHERAPY IN PATIENTS WITH MUSCLE-INVASIVE BLADDER CANCER WITH BLADDER PRESERVATION FOR THOSE PATIENTS WHOSE TUMORS HARBOR DELETERIOUS DNA DAMAGE RESPONSE (DDR) GENE ALTERATIONS

Eligibility Criteria (see Section 3.0)

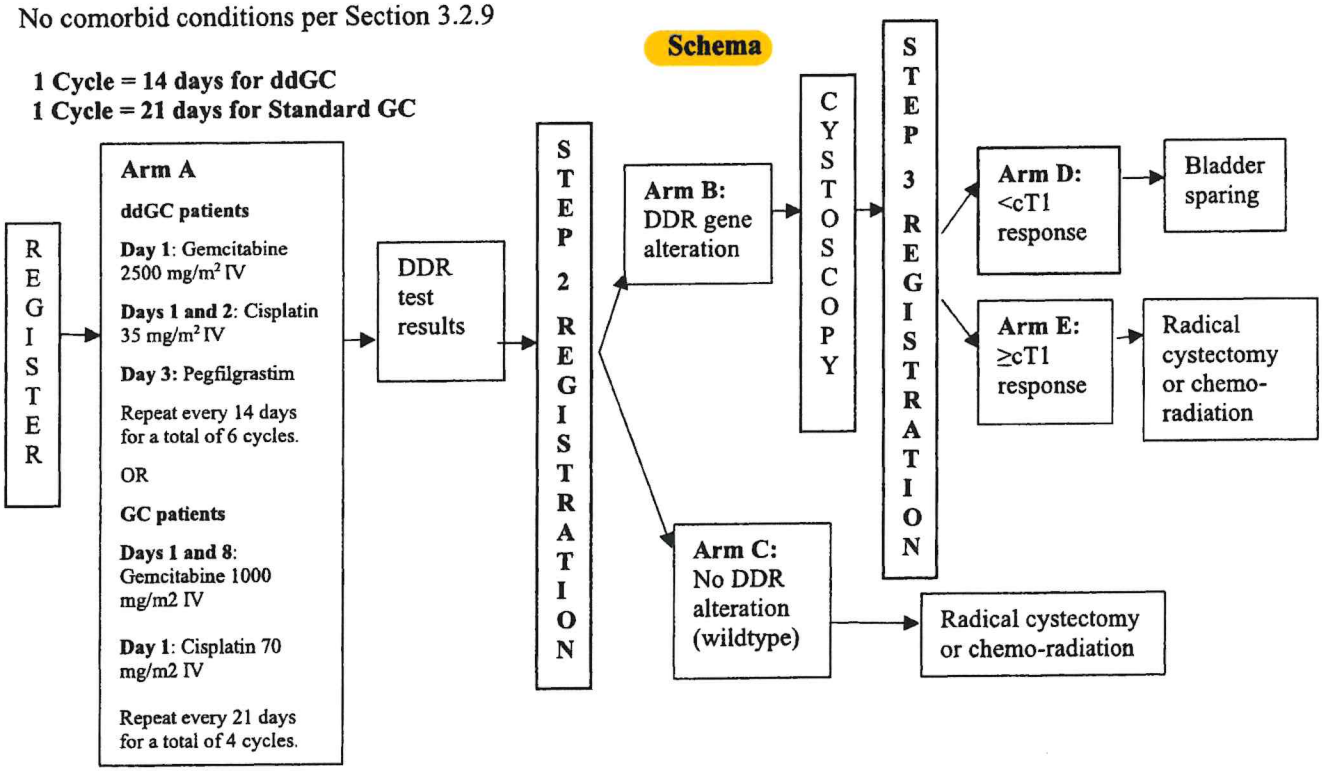
Histologically confirmed urothelial carcinoma of the bladder
10-20 unstained slides or 1 FFPE block from pre-treatment TUR available
Clinical stage T2-T4aN0/xM0
Candidate for radical cystectomy
No prior systemic chemotherapy or radiation therapy for the bladder
No major surgery or RT ≤ 4 weeks
Non-pregnant and non-nursing
Age >= 18 years
ECOG PS = 0-1
No comorbid conditions per Section 3.2.9

Required Initial Laboratory Values

Absolute neutrophil count (ANC): ≥ 1000/mm^3
Platelet count: ≥ 100,000/mm^3
Calc. creatinine clearance: ≥ 55 mL/min
Total bilirubin: ≤ 1.5 x ULN
(For patients with documented Gilbert's syndrome Bilirubin ≤ 3 x ULN)
AST/ALT: ≤ 2.5 x ULN
Alkaline phosphatase: ≤ 2.5 x ULN

Schema

1 Cycle = 14 days for ddGC
1 Cycle = 21 days for Standard GC



Chemotherapy is to continue for 6 cycles or unacceptable adverse events (at least 4 cycles must be given for patients to proceed to Step 2 registration). Patients on the standard treatment (gemcitabine on days 1 and 8 and cisplatin on day 1) must receive 4 cycles to proceed to Step 2 registration. Patients will be followed for five years after completion of chemotherapy or radical cystectomy, or until death, whichever comes first.

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.